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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/061,835	01/31/2002	Frank J. Landherr	112713-115	9493
29200	7590	01/15/2004	EXAMINER	
BAXTER HEALTHCARE CORPORATION			HARAN, JOHN T	
RENAL DIVISION			ART UNIT	
1 BAXTER PARKWAY			PAPER NUMBER	
DF3-3E			1733	
DEERFIELD, IL 60015			DATE MAILED: 01/15/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,835

Applicant(s)

LANDHERR ET AL.

Examiner

John T. Haran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 47-86 and 88 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30-33 and 35-46 is/are allowed.
- 6) ☒ Claim(s) 15, 17-29 and 87 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II claims 15-46 and 87 in the response sent on 11/17/03 is acknowledged.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 6/26/02 and 2/4/03 have been considered by the examiner. It is noted that items C5-C15 on the IDS submitted on 6/26/02 have been considered but have been lined through because they do not contain the web site addresses of the printed web pages.

The information disclosure statement filed 1/27/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 17-19, 25-29, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-19 recite the limitation "the prism". There is insufficient antecedent basis for this limitation in the claims because they all depend from claim 15 and claim 15 does not claim a prism.

Claim 25 is indefinite because it appears the claim is requiring the laser unit be capable of connecting the two tube ends together but it is unclear how this is possible. It appears that it is the tube holders that are moved to move the tube ends together and connect them as claimed in claim 15.

Claim 34 recites the limitation "the sensor". There is insufficient antecedent basis for this limitation in the claim. It appears the claim should depend from claim 31 rather than claim 30.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 15, 17, 18, 20-24 and 87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al in view of JP 53-14772 and Savitski et al (U.S. Patent 6,596,122) taken with Emmelmann (U.S. Patent 6,201,211).

Ivansons et al is directed to a device of the connection of plastic tube comprising a pair of tube holders adapted to receive a flexible tube end and adapted to urge the two tube ends together after the two tube ends have heated to join the heated tube ends together to form a weld and a heated wafer for insertion between two spaced apart

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tube ends held in the tube holders for heating the tube ends (Figure 15 and Column 8, lines 54-62). Ivansons et al is silent towards using a laser beam to heat the ends of the plastic tubes.

One skilled in the art would have readily appreciated that welding devices that use laser beams to heat plastic parts for welding them together are well known and conventional as shown for example in JP 53-14772 and Savitski et al. JP 53-14772 teaches heating spaced apart plastic plates with a laser and then pushing the heated ends together to weld the plastic plates together (information obtained from English abstract and PTO translator). Savitski et al teaches butt joining plastic pipe ends together by heating with laser (Column 6, lines 23-50). One skilled in the art would have readily appreciated that a heating wafer and a laser are alternate expedients for heating that are obvious over one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laser beam as the heating implement in the device of Ivansons et al because as suggested in JP 53-14772 and Savitski et al lasers are known heating implements for welding plastic parts and are an alternate expedient to a heating wafer.

JP 53-14772 and Savitski et al are silent towards having a laser optics assembly capable of changing a direction of the laser beam, however such is well known and conventional in the laser art, as shown for example in Emmelmann et al. Emmelmann et al teaches having a laser optics assembly for changing the direction of a laser beam in a welding device including a collimation lens and a pivotable mounted prism (See Figure 4 and Column 5, lines 9-16). It would have been obvious to one of ordinary skill

in the art to have a laser optics assembly capable of changing a direction of the laser beam in order to ensure adequate heating of both tube ends in the device of Ivansons et al, as modified above to have a laser unit for the heat source, as suggested in Emmelmann et al.

Regarding claim 17, Emmelmann teaches having a collimator between a laser unit and a prism (See Figure 4).

Regarding claims 18 and 87, Emmelmann teaches that the prism is not located between the works being heated and welded together (See Figure 4).

Regarding claim 20, one skilled in the art would have readily appreciated that the laser is capable of sufficiently heating the tubes ends to sterilize them.

Regarding claim 21, the laser optics assembly of Emmelmann is capable of changing the plane of the laser beam since it is pivotally mounted and can be rotated 360 degrees (Column 5, lines 9-16).

Regarding claims 22 and 23, it is known to use light pipes to direct laser beams as shown for example in Savitski et al (Column 6, line 47). One skilled in the art would have been motivated to use a y-shaped light guide to split the laser beam to either tube end rather than waste energy by applying laser through the gap between the tube ends as in JP 53-14772 (See Figures) and because it is more efficient than direct the laser to one tube end and then the other tube end. It would have been obvious to have a y-shaped light pipe in the device of Ivansons et al, as modified above.

Regarding claim 24, one skilled in the art would have readily appreciated that the device of Ivansons et al, as modified above, is capable of exerting sufficient heat and pressure to obtain a hermetic seal.

7. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al in view of JP 53-14772 and Savitski et al (U.S. Patent 6,596,122).

Ivansons et al is directed to a device of the connection of plastic tube comprising a pair of tube holders adapted to receive a flexible tube end and adapted to urge the two tube ends together after the two tube ends have heated to join the heated tube ends together to form a weld and a heated wafer for insertion between two spaced apart tube ends held in the tube holders for heating the tube ends (Figure 15 and Column 8, lines 54-62). Ivansons et al is silent towards having a sensor for analyzing the connection between the tube ends.

One skilled in the art would have readily appreciated that a perfect weld is desired without any leaks or imperfections when welding tube ends because the purpose of a tube is to have liquid flow through it and it is undesirable to have leaks. One skilled in the art would have readily appreciated performing a visual inspection or having a sensor for doing the same. Additionally Ivansons et al teaches having clamp sensors for ensuring the clamps of the tube holders are closed and the tubes are in the clamps, a controller for testing that the tubes are correctly loaded and positioned in the clamp holders, thermocouples for monitoring the temperature, and a controller for monitoring the time the tube ends are held together to ensure adequate welding, but is

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silent towards having a sensor for analyzing the connection (Column 7, line 61 to Column 8, line 27). One skilled in the art would have readily appreciated that all the sensors and controls taught in Ivansons et al are directed towards ensuring an adequate weld between the tube ends and would have been motivated to include an additional sensor to analyze the connection as an additional check. It would have been obvious to one of ordinary skill in the art at the time the invention was made to one of ordinary skill in the art at the time the invention was made to include a sensor to analyze the connection of the two tube ends in order to additionally ensure an adequate weld.

Ivansons et al is also silent towards using a laser beam to heat the ends of the plastic tubes. One skilled in the art would have readily appreciated that welding devices that use laser beams to heat plastic parts for welding them together are well known and conventional as shown for example in JP 53-14772 and Savitski et al. JP 53-14772 teaches heating spaced apart plastic plates with a laser and then pushing the heated ends together to weld the plastic plates together (information obtained from English abstract and PTO translator). Savitski et al teaches butt joining plastic pipe ends together by heating with laser (Column 6, lines 23-50). One skilled in the art would have readily appreciated that a heating wafer and a laser are alternate expedients for heating that are obvious over one another. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laser beam as the heating implement in the device of Ivansons et al, as modified above to have a sensor for analyzing the connection, because as suggested in JP 53-14772 and Savitski et al

lasers are known heating implements for welding plastic parts and are an alternate expedient to a heating wafer.

Regarding claims 26-28, as noted above Ivansons et al teaches a tracking system for moving the two tube holders together, a positioning detector for the tubes and heat sensor for monitoring the temperature.

8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ivansons et al in view of JP 53-14772 and Savitski et al (U.S. Patent 6,596,122) as applied to claims 25-28 above, and further in view of Emmelmann (U.S. Patent 6,201,211).

JP 53-14772 and Savitski et al are silent towards having a laser optics assembly capable of changing a direction of the laser beam, however such is well known and conventional in the laser art, as shown for example in Emmelmann et al. Emmelmann et al teaches having a laser optics assembly for changing the direction of a laser beam in a welding device including a collimation lens and a pivotable mounted prism (See Figure 4 and Column 5, lines 9-16). It would have been obvious to one of ordinary skill in the art to have a laser optics assembly capable of changing a direction of the laser beam in order to ensure adequate heating of both tube ends in the device of Ivansons et al, as modified above to have a laser unit for the heat source, as suggested in Emmelmann et al.

Allowable Subject Matter

9. Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claim 19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 16, the prior art of record fails to suggest the claimed device for providing a connection between two flexible tube ends, particularly having a prism movably mounted between the two tube ends.

There is no suggestion or motivation in JP 53-14772, Savitiski et al, or Emmelmann for positioning a prism between two pieces of work being heated by laser so that the can be pushed together to form a weld.

Regarding claim 19, the prior art of record fails to suggest the claimed device for providing a connection between two flexible tube ends, particularly having a prism for reflect the laser beam to heat the two tube ends and a light pipe for directing the laser beam to weld the two tube ends together.

There is no suggestion or motivation in JP 53-14772, Savitiski et al, or Emmelmann for having a prism and a light guide for directing a laser beam while heating and welding.

12. Claims 30-33 and 35-46 are allowed. It is noted that claim 34 would be allowable if the lack antecedent basis problem noted above is fixed.

13. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to suggest the claimed device for providing a sterile connection between two flexible tube ends, particularly having a housing with slots adapted for receiving tube ends and a pair of guides positioned within the housing.

JP 6-91010 is directed to a device for aseptic splicing of flexible tubes wherein the device uses a heat wafer to heat tube ends and tube holders bring the tube ends together to form a weld and the device is contained within a housing (See Figure 2). There is no suggestion or motivation for the housing having slots on the sides for receiving tubes because it appears the operation is done with the lid of the housing open and the tubes are manually placed in the tube holders so there is no need for guides.

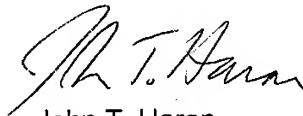
14. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **John T. Haran** whose telephone number is **(571) 272-1217**. The examiner can normally be reached on M-Th (8 - 5) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in cursive script, appearing to read "John T. Haran".

John T. Haran
Examiner
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